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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/610,313	BARNETT ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40 and 43-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *48-51* is/are allowed.

6)☒ Claim(s) *1-26,29-40,43-47* is/are rejected.

7)☒ Claim(s) *27 and 28* is/are objected to.

8)☐ Claim(s) - are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/16/05,6/17/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 5/16/05 has been entered.

Claims 1-40 and 43-51 are pending.

Applicant's traversal, the amendment to the specification and the amendment to claim 1 in paper filed on 5/16/05 is acknowledged and considered by the examiner.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 6/17/05 and 5/16/05 were filed after the mailing date of the final rejection on 6/14/04. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The later-filed application must be an

application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Instant claims 1-40 and 43-51 do not enjoy priority to co-pending US application 09/475,704 because application '704 does not provide written support for SEQ ID NO: 30-32. Figures 8-10 recited in instant claim 1 are not disclosed in '704. The Figures in '704 only go up to Figure 6 and are directed to a HIV Gag polypeptide.

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-40 and 43-51 of this application. Neither provisional application 60/114,495 nor 60/152,195 provide written description for SEQ ID NO: 30-32 in instant claims 1-40 and 43-51.

Thus, the instant application only enjoys priority to 7/5/00.

Claim Objections

Claims 27 and 28 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to the other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 27 and 28 have not been further treated on the merits.

Claims 43-46 are objected to because of the following informalities: the claims depend on a cancelled claim. Appropriate correction is required.

Claim 47 is objected to because of the following informalities: A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim, which depends from a dependent claim, should not be separated by any claim, which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n). Claim 47 is separated from claim 2. If the claims (including claim 47) become allowable the numbering of the claims would have to be amended.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 3, 7, and 47 are and claims 43-46 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 47 recites the limitation "the viral polypeptide or antigen" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Suggest amending the limitation to recite -- the viral polypeptides or antigens --.

Claim 7 recites the limitation "said transcription promoter" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claims 43-46 recite the limitation "The method of claim 42". There is insufficient antecedent basis for this limitation in the claim.

Applicant has not address this rejection. Thus, the rejection remains for the reasons of record. These claims have not been further examined because the metes and bounds of the claims are undefined.

Claim Rejections - 35 USC § 102

For the reasons set forth above, the instant application only enjoys priority to 7/5/00.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The claimed invention reads on a nucleotide sequence encoding an HIV polypeptide, wherein the nucleotide sequence encoding the HIV polypeptide encodes pol polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NOs: 30-32 and method of using the expression cassette. The claimed invention reads on a nucleotide sequence encoding an HIV polypeptide, wherein the polypeptide has 70% sequence identity to the HIV polypeptide encoded by the nucleotide sequence set forth in SEQ ID NOs: 30-32.

Determining 70% identity at the amino acid level from 90% at the polynucleotide level was based on the following: substituting 100 nucleotides of a 1,000 base pair polynucleotide sequence is a sequence with 90% identity to the 1,000 base pair polynucleotide sequence. The polypeptide sequence encoded by the polynucleotide sequence with 90% identity would have a polypeptide with 333 amino acids. Substitute one polynucleotide in 100 codons of the polynucleotide with 90% identity could give a polypeptide with 30% substitution and polypeptide having 70% sequence identity to the amino acid sequence encoded by SEQ ID NO: 30-32.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al. (US 6610476). Chang teaches a nucleic acid sequence encoding an HIV Pol polypeptide comprising a nucleotide sequence having at least 90% sequence to the sequence presented in SEQ ID NO: 30-32 of the instant claims (column 53). The sequence taught by Chang encompasses a nucleotide sequence encoding an amino acid sequence having at least 70% sequence identity to the amino acid sequence encoded by SEQ ID NO: 30-32 of the instant claims.

Claims 1, 2, 5, 6, 8, 12, 13, 22, 23, 25, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kang (US 5,858,646). Kang teaches a nucleic acid sequence encoding an HIV Pol polypeptide (SEQ ID NOs: 1-9), wherein the nucleic acid is a nucleotide sequence having at least 90% sequence to the sequence presented in SEQ ID NO: 30-32 of the instant claims (column 2 of '646). The sequence taught by Kang encompasses a nucleotide sequence encoding an amino acid sequence having at least 70% sequence identity to the amino acid sequence encoded by SEQ ID NO: 30-32 of the instant claims. Kang teaches that a HIV pol gene can be expressed in a SF9

insect cell using a baculovirus (columns 2-4 of '646). Kang anticipates the limitation in instant claims 2, 23, and 26 (column 2 of '646).

Claims 1, 22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Mauclere et al. (WO 98/26075, the document is in French, US 6,509,018 is assumed to be the English equivalent of WO 98/26075 and is provided as an English translation of the WO document). Mauclere teaches a nucleic acid sequence encoding an HIV Pol polypeptide (SEQ ID NO: 6) comprising a nucleotide sequence having at least 90% sequence to the sequence presented in SEQ ID NO: 30-32 of the instant claims (column 4). The sequence taught by Mauclere encompasses a nucleotide sequence encoding an amino acid sequence having at least 70% sequence identity to the amino acid sequence encoded by SEQ ID NO: 30-32 of the instant claims. Mauclere teaches an immunogenic composition comprising one or more translational products of the nucleotide sequences (column 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,858,646) taken with Rovinski et al. (A32). Kang teaches a nucleic acid sequence encoding an HIV Pol polypeptide (SEQ ID NOs: 1-9) comprising a nucleotide sequence having at least 90% sequence to the sequence presented in SEQ ID NO: 30-32 of the instant claims (column 2). The sequence taught by Kang encompasses a nucleotide sequence encoding an amino acid sequence having at least 70% sequence identity to the amino acid sequence encoded by SEQ ID NO: 30-32 of the instant claims. Kang teaches that a HIV pol gene can be expressed in a SF9 insect cell using a baculovirus (columns 2-4). Kang teaches the limitation in instant claims 2 (column 2). However, Kang does not specifically inserting one or more viral polypeptides selected from the group consisting of Gag and Env in the baculovirus.

However, at the time the invention was made, Rovinski teaches producing a non-infectious HIV particle comprising Env gene product, Gag gene product, Pol gene product and

one antigenic marker (column 2). Rovinski teaches modifying the HIV gene product by deleting the coding regions encoding reverse transcriptase and integrase (column 6 and Figure 8).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang taken with Rovinski, namely to produce a construct comprising a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 30-32 of the instant application further including a polynucleotide encoding an HIV Gag and Env gene product taught by Rovinski. One of ordinary skill in the art would have been motivated to combine the teachings to produce the construct because Rovinski teaches producing the construct to avoid producing and using infectious HIV particles in studies thus avoiding the risk of exposing someone to infectious HIV particles.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,858,646) taken with Robinson et al. (US 5,738,852). Kang teaches a nucleic acid sequence encoding an HIV Pol polypeptide (SEQ ID NOs: 1-9) comprising a nucleotide sequence having at least 90% sequence to the sequence presented in SEQ ID NO: 30-32 of the instant claims (column 2). The sequence taught by Kang encompasses a nucleotide sequence encoding an amino acid sequence having at least 70% sequence identity to the amino acid sequence encoded by SEQ ID NO: 30-32 of the instant claims. Kang teaches that a HIV pol gene can be used in an immunogenic composition (columns 2-4). However, Kang does not specifically inserting one or more cytokines in the composition.

However, at the time the invention was made, Robinson teaches producing a vector comprising a cytokine and a viral antigen and using the vector in an enhanced immune response method (columns 4-5 and 15-18).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang taken with Robinson, namely to produce a composition comprising a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 30-32 of the instant application further including a polynucleotide encoding a cytokine. One of ordinary skill in the art would have been motivated to combine the teachings to produce the composition because Robinson teaches adding a cytokine to the composition will improve the immunogenic property of the composition (column).

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,858,646) taken with Corbin et al. (US 6,489,542). Kang teaches a nucleic acid sequence encoding an HIV Pol polypeptide (SEQ ID NOs: 1-9) comprising a nucleotide sequence having at least 90% sequence to the sequence presented in SEQ ID NO: 30-32 of the instant claims (column 2). The sequence taught by Kang encompasses a nucleotide sequence encoding an amino acid sequence having at least 70% sequence identity to the amino acid sequence encoded by SEQ ID NO: 30-32 of the instant claims. Kang teaches that a HIV pol gene can be expressed in a SF9 insect cell using a baculovirus (columns 2-4). Kang teaches the limitation in instant

claims 2 (column 2). However, Kang does not specifically using all of the elements recited in instant claim 6.

However, at the time the invention was made, the control elements in instant claim 6 were readily available to one of ordinary skill in the art for producing a construct as exemplified by Corbin (columns 22-26, 51-53, and 109-110).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang taken with Corbin, namely to produce a construct with the control elements set forth in instant claims 5 and 6 comprising the plasmid taught by Kang. One of ordinary skill in the art would have been motivated to combine the teachings, as a matter of designer's choice, because the control elements were readily available to one ordinary skill in the art for use in expressing a nucleotide sequence from a construct in a cell.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1, 5, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,858,646) taken with Corbin et al. (US 6,489,542) as applied to claims 1, 5, and 6 above, and further in view of either Sikic et al. (US 5,830,697) or Dubensky et al. (US 6,391,632).

However, Kang taken with Corbin do not specifically teach the construct comprising the promoters set forth in instant claim 7.

However, at the time the invention was made, the promoters recited in instant claim 7 were readily available to one of ordinary skill in the art as taught by Dubensky. The promoters

selected from MMLV-LTR and HIV-LTR (Sikic et al., column 4) and CMV, CMV-intron A, SV40, RSV, MMLV-LTR, and metallothionein (Dubensky et al., columns 22, 26, and 87-88).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang and Corbin taken with either Sikic or Dubensky, namely to produce a construct with the control elements set forth in instant claim 7. One of ordinary skill in the art would have been motivated to combine the teachings, as a matter of designer's choice, because the promoters were readily available to one ordinary skill in the art for expressing a nucleic acid in a cell.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1, 8-12, and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,858,646) taken with ATCC catalog of cell lines and hybridomas (7th edition, Maryland, 1992, pages 70, 79, 148, 150, 158, 164, 194, 299, 308, and 456). Kang teaches a nucleic acid sequence encoding an HIV Pol polypeptide (SEQ ID NOs: 1-9) comprising a nucleotide sequence having at least 90% sequence to the sequence presented in SEQ ID NO: 30-32 of the instant claims (column 2). The sequence taught by Kang encompasses a nucleotide sequence encoding an amino acid sequence having at least 70% sequence identity to the amino acid sequence encoded by SEQ ID NO: 30-32 of the instant claims. Kang teaches that a HIV pol gene can be expressed in a SF9 insect cell using a baculovirus (columns 2-4). Kang teaches the limitation in instant claims 2 (column 2). However, Kang does not specifically teach using all of the cells recited in instant claims 9-12 and 16-21.

However, at the time the invention was made, the cell lines in instant claims 9-12 and 16-21 were readily available to one of ordinary skill in the art as exemplified by ATCC catalog (pages 70, 79, 148, 150, 158, 164, 194, 299, 308, 456) for making a cell comprising a plasmid. In addition, the instant specification further supports that the several of the cell lines recited in the instant claims were readily available at the time the invention was made from ATCC (page 39).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang taken with the ATCC catalog, namely to produce the cell lines in the instant claims comprising the construct taught by Kang. One of ordinary skill in the art would have been motivated to combine the teachings, as a matter of designer's choice, to insert the construct taught by Kang in any cell set forth in the instant claims for producing the polypeptide and because the cell lines were readily available to one ordinary skill in the art.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1, 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,858,646) taken with Helting et al. (US 5,470,720). Kang teaches a nucleic acid sequence encoding an HIV Pol polypeptide (SEQ ID NOs: 1-9) comprising a nucleotide sequence having at least 90% sequence to the sequence presented in SEQ ID NO: 30-32 of the instant claims (column 2). The sequence taught by Kang encompasses a nucleotide sequence encoding an amino acid sequence having at least 70% sequence identity to the amino acid sequence encoded

by SEQ ID NO: 30-32 of the instant claims. Kang teaches that a HIV pol gene can be expressed in a SF9 insect cell using a baculovirus (columns 2-4). Kang teaches the limitation in instant claims 2 (column 2). However, Kang does not specifically teach using a cell recited in instant claim 14.

However, at the time the invention was made, the cell line in instant claim 14 was readily available to one of ordinary skill in the art for expressing an HIV polypeptide as exemplified by Helting et al. (column 10).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang taken with Helting et al., namely to produce the cell line in instant claim 14 comprising the polynucleotide taught by Kang. One of ordinary skill in the art would have been motivated to combine the teachings, as a matter of designer's choice, to insert a construct suitable for the cell set forth in instant claim 14 and produce the polypeptide and because the cell line and method of producing the cell line were readily available to one of ordinary skill in the art.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1, 8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,858,646) taken with Adams et al. (C6). Kang teaches a nucleic acid sequence encoding an HIV Pol polypeptide (SEQ ID NOs: 1-9) comprising a nucleotide sequence having at least 90% sequence to the sequence presented in SEQ ID NO: 30-32 of the instant claims (column 2). The sequence taught by Kang encompasses a nucleotide sequence encoding an amino acid sequence

having at least 70% sequence identity to the amino acid sequence encoded by SEQ ID NO: 30-32 of the instant claims. Kang teaches that a HIV pol gene can be expressed in a SF9 insect cell using a baculovirus (columns 2-4). Kang teaches the limitation in instant claims 2 (column 2). However, Kang does not specifically teach using the cell line recited in instant claim 15.

However, at the time the invention was made, the cell line in instant claim 15 was readily available to one of ordinary skill in the art for expressing an HIV polypeptide as exemplified by Adams et al. (pages 68-70).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang taken with Adams et al., namely to produce the cell lines in instant claim 15 comprising the construct taught by Kang. One of ordinary skill in the art would have been motivated to combine the teachings, as a matter of designer's choice, to insert and/or use a construct suitable for the particular type of cell set forth in instant claim 15 and produce the polypeptide and because the cell line and method of producing the cell line were readily available to one of ordinary skill in the art.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1, 22, 29, 30-32, 34, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,858,646) taken with Tobin et al. (A49). Kang teaches a nucleic acid sequence encoding an HIV Pol polypeptide (SEQ ID NOs: 1-9) comprising a nucleotide sequence having at least 90% sequence to the sequence presented in SEQ ID NO: 30-32 of the instant claims (column 2). The sequence taught by Kang encompasses a nucleotide sequence

encoding an amino acid sequence having at least 70% sequence identity to the amino acid sequence encoded by SEQ ID NO: 30-32 of the instant claims. Kang teaches that a HIV pol gene can be expressed in a SF9 insect cell using a baculovirus (columns 2-4). Kang teaches the limitation in instant claims 2 (column 2). Kang teaches that a HIV pol gene can be used in an immunogenic composition (columns 2-4). However, Kang does not specifically teach the steps for using the construct to generate an immune response in a subject.

However, at the time the invention was made, generating an immune response in a mammal (e.g., human) comprising introducing a nucleic acid encoding an HIV chimeric polypeptide into the mammal was well known to one of ordinary skill in the art as exemplified by Tobin et al. (columns 4, 12, 17, and 40-41). The chimeric polypeptide can include HIV Gag, Env, and Pol (columns 4 and 31-44). In addition, Tobin teaches using a viral vector (e.g., retroviral vector) or liposome (non-viral vector) to deliver the nucleic acid to a cell in vivo (columns 3-5, 11, 17-20, and 21-24).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang taken with Tobin et al., namely to generate an immune response in a human comprising the HIV pol gene taught by Kang. One of ordinary skill in the art would have been motivated to combine the teachings to generate an immune response in a human using the HIV pol gene taught by Kang to study the immune response to HIV pol in the human as exemplified by Tobin (columns 12, 17, and 20).

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang taken with Tobin et al., namely to generate an immune response in a mammal comprising a liposome comprising the

HIV pol gene taught by Kang. One of ordinary skill in the art would have been motivated to combine the teachings to generate an immune response in a mammal using a liposome because liposomes are well know to one of ordinary skill in the art for delivering a nucleic acid to a cell in vivo as exemplified by Tobin (columns 19 and 22).

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang taken with Tobin et al., namely to generate an immune response in a mammal comprising administering a retroviral vector comprising the HIV pol gene taught by Kang. One of ordinary skill in the art would have been motivated to combine the teachings to generate an immune response in a mammal using a retroviral vector because retroviral vectors are well known for one of ordinary skill in the art for delivering a nucleic acid to a cell in vivo as exemplified by Tobin (columns 11-12, 17-19 and 21-24).

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1, 22, 29, 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,858,646) taken with Tobin et al. (A49) as applied to claims 1, 22, 29, 30, 32, 34, and 38-40 above, and further in view of Marrow (US 5,622,705). However, Kang and Tobin do not specifically teach using a Sinbis virus to deliver the plasmid to the mammal.

However, at the time the invention was made, Marrow teaches that one of ordinary skill in the art could generate an immune response using Sinbis virus comprising a nucleic acid (columns 9 and 10).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang taken with Tobin et al. in further view of Marrow, namely to generate an immune response in a mammal comprising administering a Sinbis-virus derived vector comprising the HIV pol gene taught by Kang. One of ordinary skill in the art would have been motivated, as a matter of designer's choice, to combine the teachings to generate an immune response in a mammal using the Sinbis-virus to study the immune response to HIV pol in the mammal because the Sinbis-virus is used by one of ordinary skill in the art for expressing a nucleic acid in a mammal.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1, 22, 29, 30, 32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,858,646) taken with Tobin et al. (A49) as applied to claims 1, 22, 29, 30, 32, 34, and 38-40 above, and further in view of Kafri et al. (Nat. Genet. 1997, 17:abstract). However, Kang and Tobin do not specifically teach using a lentiviral vector to deliver the plasmid to the mammal.

However, at the time the invention was made, Kafri et al. teach that one of ordinary skill in the art could use a lentiviral vector to express a nucleic acid in vivo (abstract).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang and Tobin taken with Kafri et al, namely to generate an immune response in a mammal comprising administering a lentiviral vector comprising the HIV pol gene taught by Kang. One of ordinary skill in the art would have

been motivated, as a matter of designer's choice, to combine the teachings to generate an immune response in a mammal using the lentiviral vector to study the immune response to HIV pol in the mammal because the lentiviral vector was well known to one of ordinary skill in the art for expressing a nucleic acid in a mammal.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1, 22, 30, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,858,646) taken with Tobin et al. (A49) as applied to claims 1, 22, 29, 30, 32, 34, and 38-40 above, and further in view of Lai et al (DNA and Cell Biology, 14, 1995, 643-651). However, Kang and Tobin do not specifically teach using a gene gun to deliver a particulate carrier comprising gold or tungsten coating the plasmid to the mammal.

However, at the time the invention was made, Lai teaches that DNA coated onto heavy tungsten or gold particles can be delivered to an animal using a gene gun (page 643). Lai teaches that using the gene gun saves times, money, and labor (page 643).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang taken with Tobin et al. in further view Lai, namely to generate an immune response in a mammal comprising gene gun delivery to a mammal a plasmid coated onto heavy tungsten or gold. One of ordinary skill in the art would have been motivated, as a matter of designer's choice, to combine the teachings to generate an immune response in a mammal using the gene to study the immune response to HIV pol in the

mammal and because the gene gun method saves time, money and labor as taught by Lai (page 643).

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang (US 5,858,646) taken with Shiver et al. (AE-1). Kang teaches a nucleic acid sequence encoding an HIV Pol polypeptide (SEQ ID NOs: 1-9) comprising a nucleotide sequence having at least 90% sequence to the sequence presented in SEQ ID NO: 30-32 of the instant claims (column 2). The sequence taught by Kang encompasses a nucleotide sequence encoding an amino acid sequence having at least 70% sequence identity to the amino acid sequence encoded by SEQ ID NO: 30-32 of the instant claims. Kang teaches the limitation in instant claims 2 and 22-23 (columns 2 and 3). However, Kang does not specifically teach making the composition with an adjuvant.

However, at the time the invention was made, combing an adjuvant with an immunogenic composition was well known to one of ordinary skill in the art as exemplified by Shiver (pages 23 and 38).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kang taken with Shiver, namely to make a composition comprising a nucleic acid encoding one or more HIV Pol polypeptides and an adjuvant. One of ordinary skill in the art would have been motivated, as a matter of designer's choice, to combine the teachings to produce the composition because one of ordinary skill in the

art understands that it was routine to also use an adjuvant when administering the composition in vivo.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 5-11, and 19-21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 16-22, and 30-32 of copending Application No. 10/190,435. Both sets of claims are directed to an expression cassette comprising a polynucleotide sequence encoding an HIV polypeptide and cells comprising the expression cassette. The polynucleotide sequence SEQ ID NO: 9 in the claims of '435 has at least 90% sequence identity to SEQ ID NO: 30-32 in the instant claims. (99.2% sequence identity with SEQ ID NO: 32). Furthermore, the limitations in instant claims 5-11 and 19-21 are the same as the limitations recited in claims 16-22 and 30-32 of '435.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1, 5-11, and 19-21 are directed to an invention not patentably distinct from claims 1, 16-22, and 30-32 of commonly assigned US application 10/190,435. Specifically, for the reasons set forth under the provisional double patenting rejection.

The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Response to Arguments

Applicant's arguments, see pages 8-11, filed 5/16/05, with respect to 112 first paragraph written description have been fully considered and are persuasive. The rejection of claims 1-40 and 47 has been withdrawn because the instant polynucleotide sequences recite a structure and function and the function can tolerate many modifications and the structure of an HIV Pol is well known in the prior art as stated in the Declaration by Dr. Donnelly's filed on 9/8/03.

Applicant's arguments, see pages 8-11, filed 5/16/05, with respect to 112 first paragraph enablement have been fully considered and are persuasive. The rejection of claims 1-40 and 47 has been withdrawn because several polynucleotide sequences comprising a nucleotide sequence encoding an HIV Pol polypeptide were well known in the art at the time the invention was made (See US 6,602,705 and prior art rejections of record) and the skilled artisan can make a sufficient number of species to represent the genus of polynucleotide sequence (See Declarations of Records, filed on 9/8/03 and 12/27/02).

Applicant's arguments filed 5/16/05 have been fully considered but they are not persuasive to overcome the provisional obviousness type double patenting rejection. However, the provisional rejection of claims 48-51 over claims 1, 71, 72, and 91 of co-pending Application No. 09/899,575 (SEQ ID NO: 30) has been withdrawn because the claims of '575 are now directed to a non-elected invention and are currently not pending in the application '575.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure (WO 90/10230). The WO document is the international application for Kang (US 5,858,646) already cited in a prior art rejection. Since the WO document and the US patent embrace the same embodiment and both have 102(b) dates, the US patent will be used in the rejection.

Claims 48-51 are in condition for allowance because the claims are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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